IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):	Sidney Smith et al.
Appl. No.:	09/813,351
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Title:	LARGE VOLUME FLEXIBLE CONTAINER
Art Unit:	3727
Examiner:	Jes F. Pascua
Docket No.:	CRTS-5679 (0112713-968)

Assistant Commissioner of Patents

Washington, D.C. 20231

AFFIDAVIT OF SIDNEY T. SMITH UNDER 37 C.F.R. § 1.132

Sir:

I, Sidney T. Smith, hereby state as follows:

1. My education is as follows: I have a Bachelor of Science degree in Chemistry and have completed graduate coursework in Chemical and Biomedical Engineering and Biophysical Chemistry. My work experience includes over 20 years in the design and development of flexible container technology for medical applications, biopharmaceutical solutions, and the biosciences. In addition, I have presented numerous articles on flexible barrier container technology at several industry symposiums.

2. I am one of the named inventors of the above-identified patent application and I am therefore familiar with the inventions disclosed therein. I have recently reviewed the claims of the patent application as they are currently pending. A copy of the pending claims is attached hereto at Tab A.

3. One of the problems with conventional flexible containers for containing large volumes of bio-pharmaceutical solutions of at least 200 liters is that hydraulic forces such as fluid stress and shear that occur within the container, particularly during container transport, are significant enough to rupture the container seams. The present invention is directed to a large

volume flexible container with an improved end panel design that significantly strengthens the container making it more resistant to rupture. Accordingly, in part, the claimed invention provides a large volume flexible container having end segments wherein the angle between the tapered edge of the end segment and the panel peripheral edge is between 135.01° to 138°. This angle range enables the container end panels to extend beyond the plane formed by the sleeve ends. This extended end panel configuration enables the hydraulic stress imposed upon the filled flexible container to be transferred to a support container in which the flexible container is placed.

4. Through a series of experiments, I surprisingly and unexpectedly discovered that by forming an angle of 135.01° to 138° between the panel peripheral edge and the end segment tapered edge, I was able to produce a wrinkle-free large volume flexible container with improved strength and improved resistance to rupture. Providing an angle between 135.01° and 138° permits the end panels to extend outwardly beyond the plane defined by the panel sleeve ends when the container is filled. The outwardly extending end panel, or the "pent roof" feature of the container, provides additional material at the end panel apex forming a flexible container with a wetted surface area that equals or exceeds the wetted surface area of the support container. The outwardly extending end panel thereby reduces the amount of hydraulic stress placed upon the filled container by allowing the hydraulic stress to be transferred to the support container. The angle range of 135.01° to 138° further unexpectedly provides a flexible container that does not wrinkle when placed into the support container.

5. When I prepared large volume flexible containers having an angle less than 135.01°, the end panels did not extend beyond the plane formed by the panel sleeve ends. Consequently, the flexible containers carried excessive stress in the seams and could not transfer the stress to the support container. These flexible containers were prone to rupture. The containers I prepared having an angle greater than 138° exhibited wrinkling when placed in the support container. Wrinkling is deleterious as it prevents proper filling and drainage of the fluid contents into and from the flexible container. As a result of my research and experimentation, I have discovered that the angle range of 135.01° to 138° between the tapered edge of the end segment and the panel peripheral edge produces containers for holding at least 200 liters of fluid

with the unexpected advantages of i) rupture resistant end panels and ii) wrinkle-free filling and draining.

6. A reference relied upon by the Patent Office is U.S. Patent No. 5,988,422 to Vallot (*Vallot*). *Vallot* discloses a parallelepiped-shaped sachet for transporting bio-pharmaceutical liquids. The end panels of the *Vallot* container are formed by cutting the edges of the film at a 45° ±15° angle relative to the vertical axis of the sachet. This translates to an angle range of 120°-150° between the panel peripheral edge and the end segment tapered edge. *Vallot*, however, does not provide a single example of a container wherein the angle is greater than 45°. Conversely, *Vallot* states that the welds on the bottom face and the top face of the parallelepiped sachet are parallel. This clearly indicates that the angle is exactly 45°.

7 Moreover, *Vallot* provides no disclosure regarding a container with end panels that extend beyond the plane defined by the panel ends. Provision of a parallelepiped container requires the *Vallot* end panels to be coplanar with the plane defined by the panel ends. Accordingly, *Vallot's* end panels do not extend beyond the plane defined by the panel ends. In addition, *Vallot* discloses that the flexible container "conforms exactly to the geometry" (col. 5 lines 53-56) of the support container in which it is placed. This further demonstrates that the end panels of the *Vallot* container do not extend beyond the plane defined by the panel ends and further indicates that the angle of the *Vallot* container is not greater than 45°. Regardless of the disclosure of an angle range of 45° ± 15°, it is apparent that *Vallot* fails to recognize the need to transfer stress from the flexible container to the support container and subsequently fails to provide a solution to this need. *Vallot* simply discloses a parallelepiped container wherein the angle between the panel peripheral edge and the end segment tapered edge is exactly 135°. As one skilled in the art reviewing *Vallot*, I would not be taught nor would I be led to construct a large volume flexible container with an end panel that outwardly extends beyond the plane defined by the fold line of each panel. Nor would I be led to construct a large volume flexible container with the angle range of 135.01° to 138° between the panel peripheral edge and the end segment tapered edge that permits stresses on the filled flexible container to be transferred to the support container and reinforcing the end panels while simultaneously providing a flexible container that does not wrinkle during filling and draining.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made upon information and belief are believed to be true; and further that these statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of any patent that may issue from this application.

FURTHER AFFIANT SAYETH NOT:

Sidney T. Smith

7 MARCH 2005

Date